

Subpart C—Appearance and Participation

§ 12.40 Appearance.

(a) A person who has filed a notice of participation under § 12.45 may appear in person or by counsel or other representative in any hearing and, subject to § 12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in § 12.90.

§ 12.45 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under § 12.35, a person desiring to participate in a hearing is to file with the Division of Dockets Management under § 10.20 a notice of participation in the following form:

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

NOTICE OF PARTICIPATION

Docket No. _____

Under 21 CFR part 12, please enter the participation of:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

Service on the above will be accepted by:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) _____

(b) An amendment to a notice of participation should be filed with the Division of Dockets Management and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for non-participation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 12.85 or the prehearing order issued under § 12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

[44 FR 22339, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981; 59 FR 14364, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

§ 12.50 Advice on public participation in hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Deputy Commissioner for Policy (HF-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or telephone 301-443-3480. The staff of the Associate Commissioner for Regulatory Affairs will attempt to respond promptly to all inquiries from members of the public, as well as to simple requests for information from participants in hearings.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the Administrative Law Judge (HF-3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) *Legal advice to individuals.* FDA does not have the resources to provide legal advice to members of the public concerning participation in hearings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Deputy Commissioner for Policy (HF-22) will not